

2. Claim 4 was rejected under 35 U.S.C. § 112 (second paragraph) as allegedly being vague and indefinite for recitation of the term “sufficient time” in the claim language.

3. Claims 20-23 were rejected under 35 U.S.C. § 112 (first paragraph) for purportedly failing to provide an enabling disclosure because the specification lacks complete deposit information for the clone CRY 104.

4. Claims 1-8 and 16-17 were rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by McDonald *et al.*, (1995).

5. Claims 9-15 and 18-19 were rejected under 35 U.S.C. § 103(a) for purportedly being unpatentable over McDonald *et al.*, (1995) in view of Riggs *et al.*, (1994).

## **II. Objection under 37 C.F.R. § 1.75(c)**

Applicants have canceled claim 21, therefore the rejection to this claim is moot.

## **III. Rejections under 35 U.S.C. § 112**

The Office Action rejected Claim 4 under 35 U.S.C. § 112 (second paragraph) as being vague and indefinite for recitation of the term “sufficient time” in the claim language. Applicants respectfully submit that one skilled in the art, after reading the disclosure of the invention, would need at most, only to perform routine experimentation to elucidate what constitutes a “sufficient time” to generate the oocyst antigen preparation. Specifically, Applicants respectfully bring to the Examiner’s attention the pretreatment protocol set forth on page 3, lines 7-10 of the specification, wherein clear guidance as to the boiling time is provided (*i.e.*, “when a concentration of 0.5% (w/v) SDS is used, boiling for one hour has been found to be particularly suitable”). Applicants also bring to the attention of the Examiner that this “pretreating step” achieves removal of the surface layer of the oocysts and respectfully submit that this could be readily detected by, for example, microscopy. Applicants therefore respectfully request that the rejection be withdrawn because the term “sufficient time” is adequately defined in the specification to one skilled in the art.

The Office Action rejected claims 20-23 under 35 U.S.C. § 112 (first paragraph) for failing to provide an enabling disclosure because the specification lacks complete deposit information for the clone CRY 104. Applicants respectfully request the Examiner hold this rejection in abeyance until allowable subject matter has been found with the understanding that the necessary information will be provided at such time.

#### **IV. Rejection under 35 U.S.C. § 102(b)**

Claims 1-8 and 16-17 were rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by McDonald *et al.*, (1995). Applicants respectfully submit that this reference, which is directed to methods of producing both IgM and IgG antibodies, fails to disclose the methods of the present invention. In particular, the reference does not disclose the pretreatment of the *Cryptosporidium* oocyst to prepare a partially purified oocyst antigen preparation.

More specifically, the disclosure in McDonald *et al.*, (1995) is directed to an immunogold ultrastructural study of *Cryptosporidium parvum*-infected mouse intestinal cells, wherein it was found that an IgM monoclonal antibody (1B5) reacted with the oocyst wall, an IgG monoclonal antibody (2C3), with the whole sporozoite and another IgM monoclonal antibody (2B2) with the sporozoite surface. There is no discussion, however, of any oocyst pretreatment with an agent so as to remove the surface layer of the oocysts to form an oocyst antigen preparation. In contrast, Applicants have found that in order to obtain a suitable oocyst wall antigen preparation, the oocyst wall should be separated from internal sporozoite components (see page 4, lines 1-7 of the specification).

In addition, Applicants respectfully submit that the IgG monoclonal antibody (2C3) binds to the “whole sporozoite” rather than the oocyst surface as required by the present invention (see McDonald *et al.*, (1995) at page 263, second column, lines 14-16). Furthermore, McDonald *et al.*, (1995) does not disclose whether or not the IgG monoclonal antibody (2C3) is of the IgG1 subclass. In this regard, Applicants bring to the attention of the Examiner the text on page 2, lines 5-7 of the Specification, where it is stated that antibodies of the IgG1 subclass are advantageous in that they are less prone to non-specific binding. Applicants therefore

respectfully request that the rejection be withdrawn because McDonald *et al.*, (1995) does not disclose all the limitations set forth in the claims.

**V. Rejection under 35 U.S.C. § 103(a)**

The Office Action rejected Claims 9-15 and 18-19 under 35 U.S.C. § 103(a) as being unpatentable over McDonald *et al.*, (1995) in view of Riggs *et al.*, (1994). The Office Action alleges that as McDonald *et al.*, (1995) discloses a method of separating the oocyst wall from internal sporozoites, then it would have been obvious to a skilled worker to arrive at the present invention.

In response, Applicants initially submit that the reasoning set forth in the Office Action clearly involves the impermissible benefit of hindsight since there is nothing to suggest in either of the references that the use of the sonicated oocyst antigen preparation of Riggs *et al.*, (1994) nor in the method of McDonald *et al.*, (1995) that would result in the production of IgG1 subclass antibodies. Secondly, Applicants respectfully submit that the Office Action has erred in concluding that Riggs *et al.*, (1994) teaches a method of separating the oocyst wall from internal sporozoites. As set forth on page 1130, second column, lines 34-35 of this publication, it is clear that the sonicated oocyst antigen preparation comprised oocyst walls, residual bodies and sporozoites. Furthermore, at page 1937, second column, lines 11-12, it is stated that the sonicated oocyst preparation contained sporozoites.

Applicants therefore respectfully submit that Riggs *et al.*, (1994) does not disclose the separation of “at least a part of the *Cryptosporidium* oocyst wall from the internal sporozoites” as is required by the limitation in claim 9. For these reasons, Applicants respectfully submit 9-15 and 18-19 are clearly non-obvious over McDonald *et al.*, (1995) in view of Riggs *et al.*, (1994) and request that the rejection be withdrawn.

**VI. Conclusion**


In view of the foregoing, Applicants respectfully request reconsideration and the timely allowance of the pending claims. Should the Examiner feel that there are any issues outstanding

after consideration of this response, the Examiner is invited to contact Applicant's undersigned representative to expedite prosecution.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for in the attached petition, such an extension is requested and the fee should also be charged to our Deposit Account No. 50-0310.

Dated: **February 26, 2001**  
Morgan, Lewis & Bockius LLP  
Customer No. **009629**  
1800 M Street, N.W.  
Washington, D.C. 20036  
202-467-7000

Respectfully submitted  
**Morgan, Lewis & Bockius LLP**

  
Elizabeth C. Weimar  
Registration No. 44,478